

RULE

Department of Insurance Office of the Commissioner

Regulation 63—Prohibitions on the Use of Medical Information and Genetic Test Results

In accordance with the provisions of R.S. 49:950 et seq., the Administrative Procedure Act, the commissioner of Insurance hereby adopts Regulation 63. The regulation establishes the statutory prohibitions on the use of prenatal tests, genetic tests, and related genetic test information by health insurers, third party administrators, and insurance agents.

Rule

Section 1. Purpose

The purpose of this regulation is to establish the statutory prohibitions on the use of medical information including pregnancy tests, genetic tests and related genetic test information by health insurers, third-party administrators, and insurance agents.

Section 2. Authority

This regulation is issued pursuant to the authority vested in the commissioner of Insurance under the Administrative Procedure Act and R.S. 22:3, 22:10, 22:2014, 22:2002(7), 22:214(22) and (23), 22:213.6, and 22:213.7 of the *Insurance Code*.

Section 3. Definitions

Collection—obtaining a DNA sample or samples for the purpose of determining inherited or individual characteristics that can be utilized to predict the development of medical conditions in the future. *Collection* shall not mean diagnostic or medical treatment information about an existing medical condition or the prior medical condition of a person applying for or being covered by a health benefit plan.

Compulsory Disclosure—any disclosure of genetic information mandated or required by federal or state law in connection with a judicial, legislative, or administrative proceeding.

DNA—deoxyribonucleic acid including mitochondrial DNA, complementary DNA, as well as any DNA derived from ribonucleic acid (RNA). *DNA* shall not mean any medical procedure or test utilized in the practice of medicine for the purpose of diagnosing or treating a medical illness or health related condition.

Disclose—to convey or to provide access to genetic information to a person other than the individual.

Family—includes an individual's blood relatives and any legal relatives, including a spouse or adopted child, who may have a material interest in the genetic information of the individual. For purposes of providing individual or group health care coverage, the term *family* shall not be used to prevent the collection of reasonable medical information about individuals applying for health insurance coverage to perform medical underwriting based on existing or past medical conditions of those persons being insured, except *genetic information* as defined herein.

Family History/Pedigree—the medical history of blood relatives of an individual that is used to predict the possibility of developing a medical condition in the future. The term shall not include the medical history of an insured or applicant for coverage under a health benefit plan.

Genetic Analysis—the process of characterizing genetic information from a human tissue sample and does not include the performance of medical tests, including but not limited to blood tests, in the diagnosis or treatment of a medical condition.

Genetic Characteristic—any gene or chromosome, or alteration thereof, that is scientifically or medically believed to cause a disease, disorder, or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome. The term shall not apply to identification or disclosure of an individual's gender for the purposes of obtaining or maintaining insurance or establishing insurance rates.

Genetic Information—all information about genes, gene products, inherited characteristics, or family history/pedigree

that is expressed in common language. *Genetic information* does not include the medical history of an individual insured or applicant for health care coverage.

Genetic Test—any test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins in order to diagnose or identify a genetic characteristic. The determination of a genetic characteristic shall not include any diagnosis of the presence of disease, disability, or other existing medical condition.

Health Benefit Plan—any health insurance policy, plan, or health maintenance organization subscriber agreement issued for delivery in this state under a valid certificate of authority and does not include life, disability income, or long-term care insurance.

Individual—the source of a human tissue sample from which a DNA sample is extracted or genetic information is characterized.

Individual Identifier—a name, address, social security number, health insurance identification number, or similar information by which the identity of an individual can be determined with reasonable accuracy, either directly or by reference to other available information. Such term does not include characters, numbers, or codes assigned to an individual or a DNA sample that cannot singly be used to identify an individual.

Insurer—any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, health and accident insurance policy, or any other insurance contract of this type, including a group insurance plan, or any policy of group, family group, blanket, or franchise health and accident insurance, a self-insurance plan, health maintenance organization, and preferred provider organization, including insurance agents and third-party administrators, which delivers or issues for delivery in this state an insurance policy or plan. The term *insurer* does not include any individual or entity that does not hold a valid certificate of authority to issue, for delivery in this state, an insurance policy or plan. A certificate of authority to issue an insurance policy or plan for delivery shall not include a license or certificate to act as a preferred provider organization, insurance agent, or third-party administrator.

Person—all persons other than the individual or authorized agent acting on behalf of the individual, who is the source of a tissue sample and shall include a family, corporation, partnership, association, joint venture, government, governmental subdivision or agency, and any other legal or commercial entity. This shall not prevent any licensed insurance agent duly authorized to act on behalf of the individual, from completing and submitting health insurance application documents required to apply for coverage under a health policy or plan.

Research—scientific investigation that includes systematic development and testing of hypotheses for the purpose of increasing knowledge.

Storage—retention of a DNA sample or of genetic information for an extended period of time after the initial testing process. The term does not include medical history

information about insureds or persons applying for coverage under a health benefit plan.

Section 4. Applicability and Scope

Except as otherwise specifically provided, the requirements of this regulation apply to all issuers of health care policies or contracts of insurance, or health maintenance organization subscriber agreements issued for delivery in the state of Louisiana. The requirements of this regulation shall not impinge upon the normal practice of medicine or reasonable medical evaluation of an individual's medical history for the purpose of providing or maintaining health insurance coverage. The requirements of this regulation address the use of medical information, including use of genetic tests, and genetic information for the purpose of issuing, renewing, or establishing premiums for health coverage. The provisions of this regulation do not apply to any actions of an insurer or third parties dealing with an insurer taken in the ordinary course of business in connection with the sale, issuance or administration of a life, disability income, or long-term care insurance policy.

Section 5. Prohibitions on the Use of Pregnancy Test Results

Any insurer shall be authorized to request medical information that verifies the pregnancy of an insured or individual applying for coverage under a health benefit plan. The results of any prenatal test, other than the determination of pregnancy, shall not be used as the basis to:

1. terminate, restrict, limit, or otherwise apply conditions to the coverage under the policy or plan, or restrict the sale of the policy or plan in force;
2. cancel or refuse to renew the coverage under the policy or plan in force;
3. deny coverage or exclude an individual or family member from coverage under the policy or plan in force;
4. impose a rider that excludes coverage for certain benefits or services under the policy or plan in force;
5. establish differentials in premium rates or cost sharing for coverage under the policy or plan in force;
6. otherwise discriminate against an insured individual or insured family member in the provision of insurance.

Section 6. Requirements for Release of Genetic Test and Related Medical Information

A. A general authorization for the release of medical records or medical information shall not be construed as an authorization for disclosure of genetic information. No insurer shall seek to obtain genetic information from an insured or applicant or from a DNA sample, without first obtaining written informed consent from the individual or authorized representative. To be valid, an authorization to disclose the results of a genetic test shall:

1. be in writing, signed by the individual and dated on the date of such signature;
2. identify the person permitted to make the disclosure;
3. describe the specific genetic information to be disclosed;
4. identify the person to whom the information is to be disclosed;
5. describe with specificity the purpose for which the disclosure is being made;

6. state the date upon which the authorization will expire, which in no event shall be more than 60 days after the date of the authorization;

7. include a statement that the authorization is subject to revocation at any time before the disclosure is actually made or the individual is made aware of the details of the genetic information;

8. include a statement that the authorization shall be invalid if used for any purpose other than the described purpose for which the disclosure is made.

B. A copy of the authorization shall be provided to the individual. An individual may revoke or amend the authorization in whole or in part, at any time. In complying with the provisions of this Section, the record holder is responsible for assuring only authorized information is released to insurers with respect to medical records that contain genetic information. The requirements of this Section shall not act to impede or otherwise impinge upon the ability of the patient's attending physician to provide appropriate and medically necessary treatment or diagnosis of a medical condition.

Section 7. Prohibitions on the Use of Medical Information and Genetic Test Results

A. No insurer shall require an applicant for coverage under a policy or plan, or an individual or family member who is presently covered under a policy or plan, to be the subject of a genetic test, release genetic test information, or to be subjected to questions relating to the medical conditions of persons not being insured under such policy or plan.

B. All insurers shall, in the application or enrollment information required to be provided by the insurer to each applicant concerning a policy or plan, include a written statement disclosing the rights of the applicant. Such statements shall be printed in 10-point type or greater with a heading in all capital letters that states: YOUR RIGHTS REGARDING THE RELEASE AND USE OF GENETIC INFORMATION. Disclosure statements must be approved by the Department of Insurance as complying with the requirements of R.S. 22:213.7 prior to utilization.

C. The results of any genetic test, including genetic test information, shall not be used as the basis to:

1. terminate, restrict, limit, or otherwise apply conditions to the coverage of an individual or family member under the policy or plan, or restrict the sale of the policy or plan to an individual or family member;

2. cancel or refuse to renew the coverage of an individual or family member under the policy or plan;

3. deny coverage or exclude an individual or family member from coverage under the policy or plan;

4. impose a rider that excludes coverage for certain benefits or services under the policy or plan;

5. establish differentials in premium rates or cost sharing for coverage under the policy or plan;

6. otherwise discriminate against an individual or family member in the provision of insurance.

Section 8. General Provisions

A. The requirements of this Section shall not apply to the genetic information obtained:

1. by a state, parish, municipal, or federal law enforcement agency for the purposes of establishing the identity of a person in the course of a criminal investigation or prosecution;

2. to determine paternity;

3. to determine the identity of deceased individuals;

4. for anonymous research where the identity of the subject will not be released because it is confidential;

5. pursuant to newborn screening requirements established by state or federal law;

6. as authorized by federal law for the identification of persons;

7. by the Department of Social Services or by a court having juvenile jurisdiction as set forth in *Children's Code* Article 302 for the purposes of child protection investigations or neglect proceedings.

B. An applicant/insured's genetic information is the property of the applicant/insured. No person shall retain genetic information without first obtaining authorization from the applicant/insured or a duly authorized representative, unless retention is:

1. for the purposes of a criminal or death investigation or criminal or juvenile proceeding;

2. to determine paternity.

C. For purposes of R.S. 22:213.7, any person who acts without proper authorization to collect a DNA sample for analysis, or willfully discloses genetic information without obtaining permission from the individual or patient as required under this regulation, shall be liable to the individual for each such violation in an amount equal to:

1. any actual damages sustained as a result of the unauthorized collection, storage, analysis, or disclosure, or \$50,000, whichever is greater;

2. treble damages, in any case where such a violation resulted in profit or monetary gain;

3. the costs of the action together with reasonable attorney fees as determined by the court, in the case of a successful action to enforce any liability under R.S. 22:213.7.

D. Any person who, through a request, the use of persuasion, under threat, or under a promise of a reward, willfully induces another to collect, store or analyze a DNA sample in violation; or willfully collects, stores, or analyzes a DNA sample; or willfully discloses genetic information in violation of R.S. 22:213.7 shall be liable to the individual for each such violation in an amount equal to:

1. any actual damages sustained as a result of the collection, analysis, or disclosure, or \$100,000, whichever is greater;

2. the costs of the action together with reasonable attorney fees as determined by the court, in the case of a successful action under R.S. 22:213.7.

E. The discrimination against an insured in the issuance, payment of benefits, withholding of coverage, cancellation, or nonrenewal of a policy, contract, plan or program based upon the results of a genetic test, receipt of genetic information, or a prenatal test other than one used for the determination of pregnancy shall be treated as an unfair or deceptive act or practice in the business of insurance under R.S. 22:1214.

F. This regulation shall be effective June 20, 1998.

James H. "Jim" Brown
Commissioner of Insurance

9806#002

RULE

Department of Insurance Office of the Commissioner

Regulation 64—Vehicle Mechanical Breakdown Insurers Cancellation Provisions

In accordance with R.S. 49:950 et seq., the Administrative Procedure Act, and as authorized by R.S. 22:3 and R.S. 22:1811, the commissioner of Insurance hereby adopts the following regulation to implement standards for the cancellation of Vehicle Mechanical Breakdown (VMB) contracts. The purpose of the regulation is to protect the interests of policyholders and to promote consumer awareness.

Regulation 64 Cancellation Provisions for Vehicle Mechanical Breakdown Insurers

Section 1. Purpose

The purpose of this regulation is to implement standard cancellation requirements in all vehicle mechanical breakdown contracts, and to ensure that all such contracts (hereafter sometimes referred to as "policies") issued, delivered or used in Louisiana are drafted in a more consistent and streamlined manner.

Section 2. Authority

This regulation is promulgated under the authority granted the commissioner by R.S. 22:1811, R.S. 22:3 and R.S. 49:950 et seq.

Section 3. Applicability and Scope

This regulation shall apply to all vehicle mechanical breakdown contracts that are in force and to insurers issuing, for delivery or use, vehicle mechanical breakdown contracts in Louisiana.

Section 4. Cancellation Standards

The following standards shall govern the requirements for the cancellation provisions of vehicle mechanical breakdown contracts.

1. All Mechanical Breakdown Insurance contracts having terms of greater than six months shall be cancelable and refundable upon request of the insured.

2. The refund method to be used shall be the sum of the digits (Rule of 78s) or a refund method that will be more favorable to the insured.

3. The return factor is determined by the number of unused months or the number of unused miles, and shall be based on the full premium (including commissions) paid by the insured.

a. The number of months shall mean the number of months from the effective date of the policy until the expiration date of the policy.

b. The number of miles shall mean the sum of the

number of miles on the odometer at the time of purchase and the policy mileage limit.

4. A cancellation fee, not to exceed \$50, may be charged, provided such fee is disclosed to the purchaser at the time of policy purchase.

5. The method of refund and any cancellation fee, shall be fully disclosed to the insured at or before the time of policy purchase by having such information printed in the policy form and the policy application, which shall be agreed to in writing, by the insured.

6. In calculating any refund requested by the insured, no deduction shall be allowed for any claim that has been paid under the contract being canceled.

7. If cancellation is requested in writing by the insured within 30 days from the date of purchase, full refund, minus the cancellation fee, if any, shall be made.

Section 5. Failure to Comply

In addition to any other penalties provided by the Louisiana Insurance Code relating to the regulation of Vehicle Mechanical Breakdown (VMB) insurers, any VMB insurer found to have violated the requirements of this regulation, may be issued a cease and desist order pursuant to R.S. 22:1810.

Section 6. Severability

If any section or provision of this regulation is held invalid, such invalidity shall not affect other sections or provisions which can be given effect without the invalid section or provision, and for this purpose the sections and provisions of the regulation are severable.

Section 7. Effective Date

This regulation shall take effect on June 20, 1998.

James H. "Jim" Brown
Commissioner of Insurance

9806#059

RULE

Department of Justice Office of the Attorney General

Nonprofit Hospital Acquisitions (LAC 48:XXV.Chapter 3)

In accordance with R.S. 49:950 et seq., the Office of the Attorney General has adopted the following rule governing the review and approval of nonprofit hospital acquisitions. The purpose of the rule is to set forth procedures for the review and authorization of nonprofit hospital acquisitions pursuant to R.S. 40:2115.11 through 2115.22.

Title 48

PUBLIC HEALTH—GENERAL

Part XXV. Mergers, Acquisitions, and Re-Organization

Chapter 3. Nonprofit Hospital Acquisitions:

Authorization for the Attorney General to Review Nonprofit Hospital Acquisitions

§301. Purpose

A. These rules are adopted in accordance with the public interest of assuring the continued existence of accessible,